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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,430	10/28/2003	Avram Scheiner	279.656US1	4468

21186 7590 01/28/2008  
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MINNEAPOLIS, MN 55402

EXAMINER
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NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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01/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/695,430

**Applicant(s)**

SCHEINER ET AL.

**Examiner**

ROBERT L. NASSER

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 20-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 20-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date 10/29/2007
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Claim 27 is objected to in that there is no antecedent basis for the implantable processor.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 5-10, 20-22, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al 20030191403. Zhou et al has a sensor measures heart rate information including R-R intervals and heart rate variability. Zhou inherently has a sensor for performing this measurement. It also has a sensor 344 for measuring physical activity. Zhou then has an information processing unit 342 which determines a recurrence score as a function of both activity and HRV data, compares the recurrence score to a baseline score, and diagnoses the health of the patient based on the comparison. Claim 3 is rejected in that Zhou uses the sensor of 4428378 as its activity sensor, which is an adaptive rate sensor. Claim 5 is rejected in that there is a telemetry circuit 330. Claim 6 is rejected in that there is a therapy circuit 212 connected to the processing circuit. Claim 7 is rejected in that Zhou also has a pulse generator (see paragraph [0026]). Claim 8 is rejected in that there is a memory stores the output signal in a computer readable code ([see paragraph 0012]). Claim 9 is rejected in that the ekg measuring sensor would be on one of the leads. Claim 10 is rejected in that there has to be a processor in processing circuitry 342, some element that processes data.

Claims 20-22 are rejected in that Zhou also teaches the method. Claim 29 is rejected in that the notification circuit 150 provides a warning.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou et al in view of Jensen et al 6752765. Jensen et al further teaches that an accelerometer is a known activity sensor. Hence, it would have been obvious to modify Jensen et al to use minute ventilation sensor, as it is merely the substitution of one known equivalent sensor for another. With respect to claim 26, Zhou et al correlates physical activity and heart rate variability, but does not state that it classifies HRV based on activity. Jensen further teaches classifying the HRV signals as being at rest or activity, based on the level of activity. Hence, it would have been obvious to modify Zhou et al to classify the data based on activity, to provide a more complete picture of the patient's condition. Claim 27 is rejected in that the data used to compare to the recurrence score is stored. Claim 28 is rejected in that the referenced data includes data from a selected population.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou et al in view of Koh et al 7207947. Koh et al further teaches that a minute ventilation sensor is a known activity sensor. Hence, it would have been obvious to

modify Jensen et al to use minute ventilation sensor, as it is merely the substitution of one known equivalent sensor for another.

Applicant's arguments filed 10/29/2007 have been fully considered but they are moot in view of the new grounds of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/  
Primary Examiner  
Art Unit 3735

RLN  
January 3, 2008